

4. Representative list of clinical trials

Now that the take-home lessons from the Shepherd study, the Bezzak study, and the Bonomi study have been reviewed, the following provides raw data on HRQoL from these clinical trials, as well as one additional clinical trial (Table 21.5).

Table 21.5 Health-related quality of life in clinical studies of non-small cell lung cancer (NSCLC)

	Instrument	HRQoL at baseline	HRQoL used as endpoint
Bezzak et al. ^a	Two instruments were used: EORTC QLQ-C30, and a lung cancer-specific questionnaire QLQ-LC13.	Yes	After 5 weeks, 9 weeks, and 3, 6, 9, and 12 months.
	Conclusion: The study compared surgery only, with surgery followed by chemotherapy. Patients in the chemotherapy arm had better scores in symptom items of nausea (P = .001) and fever (P = .1), but worse scores for numbness (P < .001), pins and needles (P = .02), and loss of hearing (P = .03).		
Bonomi et al. ^b	Functional Assessment of Cancer-Lung (FACT-L).	Yes	Taken 6, 12, and 26 weeks after the first course of chemotherapy.
	Conclusion: All three regimens demonstrated significant decreases in the scores over 6 months, but there were no significant differences between the regimens (P = .59 for the total FACT scores).		
Shepherd et al. ^c	Two instruments: EORTC QLQ-C30 (cancer in general) and EORTC QLQ-LC13 (for lung cancer).	Yes	Every 4 weeks.
	Conclusion: Analyses of the quality of life found that more patients receiving erlotinib had improvement in cough, pain, and dyspnea and in the domain of overall physical function.		
Mok et al. ^d	Functional Assessment of Cancer Therapy-Lung (FACT-L).	Yes	At week 1, and at 3-week intervals until day 127, and once every 6 weeks until disease progression, and when study drug was discontinued.
	Conclusion: Significantly more patients in the gefitinib group than in the carboplatin-paclitaxel group had improvement in quality of life (P = .01).		

^aBezzak A, Lee CW, Ding K, et al. Quality-of-life outcomes for adjuvant chemotherapy in early-stage non-small-cell lung cancer: results from a randomized trial, JBR.10. *J Clin Oncol.* 2008;26:5052–5059.

^bBonomi P, Kim K, Fairclough D, et al. Comparison of survival and quality of life in advanced non-small-cell lung cancer patients treated with two dose levels of paclitaxel combined with cisplatin versus etoposide with cisplatin: results of an Eastern Cooperative Oncology Group trial. *J Clin Oncol.* 2000;18:623–631.

^cShepherd FA, Rodrigues Pereira J, Ciuleanu T, et al. Erlotinib in previously treated non-small-cell lung cancer. *New Engl J Med.* 2005;353:123–312.

^dMok TS, Wu YL, Thongprasert S, et al. Gefitinib or carboplatin-paclitaxel in pulmonary adenocarcinoma. *New Engl J Med.* 2009;361:947–957.